9. 510(K) SUMMARY

JAN 25 2011

Submission Date: March 25, 2010

Submitter Information:

Company Name:
Or-Nim Medical Ltd.

Company Address:
1 Yodfat Street
Lod, 71291
Israel

Contact Person:
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Device Information:

Trade Name:	CerOx Model 3210F
Common Name:	Oximeter/Cerebral Oximeter/Tissue Oximeter Flowmeter, blood, cardiovascular
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700) Cardiovascular blood flowmeter (21 CFR 870.2100)
Product Code:	MUD, DPW
Regulatory Class:	II

Predicate Device: CerOx 3210, Or-Nim Medical Ltd.
Laserflo Blood Perfusion Monitor. BPM^2, Vasamedics L.L.C.

Device Description: The CerOx Model 3210F uses the well-established principles of near infrared spectroscopy (NIRS) to monitor the concentration of oxygenated hemoglobin relative to the total concentration of hemoglobin in the blood. In addition, it employs principles similar to those of Laser Doppler flowmetry to monitor the microcircular blood flow in tissue.

CerOx Model 3210F is identical to the CerOx Model 3210. It utilizes the same technical and operational methods.

Intended Use: The CerOx Model 3210F is intended to monitor oxygen saturation and blood flow in tissue

Indications for Use: The non-invasive CerOx 3210F monitor is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in a region of skeletal muscle tissue beneath the sensor. It is also intended for monitoring of microcirculation blood flow in tissue. The CerOx 3210F monitor is intended for monitoring of adults.

The prospective clinical value of data from the CerOx 3210F monitor has not been demonstrated in disease states. The CerOx 3210F monitor should not be used as the sole basis for diagnosis or therapy.

Comparison to Predicate Device: The CerOx 3210F is identical to the CerOx 3210 in hardware and operation, and has the same intended use and indications for use for tissue oximetry as the CerOx 3210. The CerOx 3210F performs an additional analysis of the light signals to enable monitoring of microcirculatory blood flow in tissue. In this respect it is substantially equivalent to the Laserflo Blood Perfusion Monitor BPM^2 for this indication.

Conclusions: The tests performed on CerOx Model 3210F support the conclusion that it remains as safe and effective as, and remains substantially equivalent to, the cleared predicate device CerOx 3210 for the monitoring of tissue blood oxygen saturation. The data presented and the tests performed also support the conclusion that the CerOx 3210F is substantially equivalent to the cleared predicate device Laserflo Blood Perfusion Monitor BPM^2, for the monitoring of microcirculation blood flow in tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Or-Nim Medical Ltd.
% Michal Balberg, Ph.D.
1 Yodfat Street
Lod, 71291, Israel

JAN 25 2011

Re: K100875
Trade/Device Name: CerOx Model 3210F
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD, DPW
Dated: December 08, 2010
Received: December 15, 2010

Dear Dr. Balberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Pinsky

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K100875

Device Name: CerOx Model 3210F

Indications for Use:

The non-invasive CerOx 3210F monitor is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in a region of skeletal muscle tissue beneath the sensor. It is also intended for monitoring of microcirculation blood flow in tissue. The CerOx 3210F monitor is intended for monitoring of adults.

The prospective clinical value of data from the CerOx 3210F monitor has not been demonstrated in disease states. The CerOx 3210F monitor should not be used as the sole basis for diagnosis or therapy.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100875

Concurrence of CDRH, Office of Device Evaluation (ODE)